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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,617	01/14/2005	Tommy Urban Skantze	1103326-0785	5110

7470 7590 09/15/2008
WHITE & CASE LLP
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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09/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,617	Applicant(s) SKANTZE ET AL.	
	Examiner S. Tran	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>all</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 07/07/08 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is rejected because it is not entirely clear when this isolating step occur, and which aqueous medium is referring to. For examining purposes, the claim is interpreted as collecting the nano-crystalline after the energy adding step, until further clarification is submitted.

Art Unit: 1618

Claims 4 and 5 recite the limitation “combined solution” in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite a “combined solution”, but a “first solution”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3-9, 12, 14-16, 18 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Kipp et al. US 6,607,784.

Kipp teaches a process for preparing submicron size particles of an organic compound. The process comprising: 1) dissolving the organic compound in the water

Art Unit: 1618

miscible first solvent to form a solution; 2) mixing the solution with an aqueous second solvent to precipitate the organic compound to form a pre-suspension; and 3) adding energy to the pre-suspension to form particles having an average effective particle size of 400 nm (abstract; column 4, lines 57-65; column 6, lines 32-41; and column 8).

Organic compound includes pharmaceutically active compound (column 5, lines 60-67).

Energy adding step includes sonicating the dispersion of amorphous particles for 15-30 minutes at temperature ranges from about -30°C to 30°C (column 7, lines 49-67; and examples). The aqueous second solvent further comprises one or more surfactants such as polyvinyl pyrrolidone and sodium dodecyl sulfate (column 6, lines 42 through column 7, lines 1-8; column 8, lines 51-67; and examples).

Claims 1, 3, 6, 12, 14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindrud et al. WO 00/44468 A1.

Lindrud teaches a process for preparing submicron size crystalline comprising: combining a solution of a pharmaceutical compound to be crystallized and an aqueous phase to form a precipitation (page 4, 2nd paragraph). Lindrud further teaches the use of surfactant (page 4, 3rd paragraph). Sonicating the precipitate to obtain submicron size crystalline (pages 4-5). Example 1 discloses upon completion of crystallization, the product is filtered, washed and dried to obtain submicron particles (the claimed isolating step). Example 1 further discloses the temperature is maintained at 2°C throughout the crystallization.

Art Unit: 1618

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipp et al. US 6,607,784.

Kipp is relied upon for the reason stated above. With respect to claim 2, Kipp does not explicitly teach nanoparticle having mean particle size of from 50-240 nm. However, it would have been obvious to one of ordinary skill in the art to modify the process of Kipp to prepare nanoparticle having the claimed size. This is because Kipp teaches the desirability of preparing particles having average effective size less than 400 nm (column 4, lines 49-56).

Kipp further does not expressly teach the rate of mixing such as rapid mixing in less than 30 seconds (10, 11, 13 and 20). However, it would have been obvious to one of ordinary skill in the art to, by routine experimentation modify the process of Kipp to obtain the claimed invention. This is because Kipp teaches that the process conditions such as rate of mixing of solution, rate of precipitation and the like can be selected/optimize (column 5, lines 49-55).

Claims 11-13, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindrud et al. WO 00/44468 A1.

Art Unit: 1618

Lindrud is relied upon for the reason stated above. Lindrud is silent as to the teaching of the rate of mixing. However, absent of evident to the contrary, the burden is shifted to applicant to show that the process of Lindrud does not provide rapid mixing. This is because Lindrud teaches a process for crystallizing submicron size particles that provides superior crystal structure when compared with particles formed by standard slow crystallization (page 2, lines 13-17).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606.

The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1618